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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation LISA HYDE and MARK HYDE, a married couple, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	No. MD-15-02641-PHX-DGC **PLAINTIFFS' STATEMENT OF AUTHORITIES IN RESPONSE TO DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

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Plaintiffs submit the following statement of authorities in support of their oral response to Defendant's motion for judgment as a matter of law.

I. Legal Standard

Judgment as a matter of law is appropriate where "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a). This is the same as the summary judgment standard. *Reeves v. Sanderson Plumbing*, 530 U.S. 133, 150 (2000).

II. Reasonable Alternative Design

Whether a proposed alternative is a reasonable one "implicates thorny questions of identity and definition, practically impossible to settle in the abstract." *Christopher v. DePuy Orthopaedics, Inc. (In re DePuy Orthopaedics, Inc.)*, 888 F.3d 753, 766 (5th Cir. 2018). Because "[t]he court can only hypothesize" whether an alternative is a modification or a different product, this issue should be resolved by the jury. *Kimball v. RJ Reynolds Tobacco Co.*, 2006 WL 1148506, at *3 (W.D. Wash. April 26, 2006) (regarding jury question whether proposed alternative was a "different product.").

Two principles emerge from review of the cases regarding proposed alternative designs. First, even alternatives that impair some utility in the original product may be considered reasonable alternatives. For example, a garbage truck with a rear loading function was a reasonable alternative to a truck with side-loading, even though the side-loading version allowed for higher productivity. *Mathis-Kay v. McNeilus Truck & Mfg.*, 2011 WL 4498386, at *22-23 (W.D.N.Y. Sep. 24, 2011). Similarly, a metal-on-plastic hip replacement was a reasonable alternative for a metal-on-metal version, even though the metal-on-metal version purportedly had more durability and lower risk of osteolysis (though these facts were disputed). *Christopher v. DePuy Orthopaedics, Inc. (In re DePuy Orthopaedics, Inc.)*, 888 F.3d 753, 767 (5th Cir. 2018). And a proposed alternative design that would prevent removal of a fork-lift safety feature, which was purposefully designed to be removable to provide "greater versatility in its operation in circumstances where there was low overhead clearance," was considered a reasonable alternative. *Gaudette v. Saint-Gobain Performance Plastics Corp.*, 2014 U.S. Dist. LEXIS 41790, at *39 (N.D.N.Y. Mar. 28, 2014).

Second, a potential way to analyze this issue is to consider the "central purpose" of a product. *Great N. Ins. Co. v. BMW of N. Am. LLC*, 84 F. Supp. 3d 630, 657 (S.D. Ohio 2015) (stating proposed alternative design that would reduce the stiffness of a high-performance vehicle was deemed reasonable because it did "not substantially impair the

usefulness or intended purpose of the vehicle," namely, "to transport people safely from place to place.").

In addressing these issues, the *In re Zimmer NexGen Knee Replacement Implant Products Liability Litigation* cases are instructive. Defendants cite *Joas v. Zimmer, Inc.*, the second bellwether case in that matter, in which there was no evidence that the proposed alternative design was safer than the product at issue, nor that it would have been safer for the plaintiff. 218 F. Supp. 3d 700, 724 (N.D. Ill. 2016). In the first bellwether case, however, the plaintiff admitted that the device at issue (the "Flex") had design features that made it better (it could flex beyond 130 degrees). *Batty v. Zimmer, Inc.*, 2015 WL 3669933, at *224-26 (N.D. Ill. June 12, 2015). As with the permanent filter proposed here, the proposed alternative device in *Batty*, (the "Standard"), had more limited function because it "was not intended for high-flexion use because it was not considered safe at flexion angles above 130 degrees." *Id.* The court, however, determined that the Standard was a reasonable alternative based on the argument, similar to Plaintiffs' here, that "the combination of Zimmer's negligent product design, inadequate testing, and promises that the product was safe for high-flexion use posed an unreasonable risk of harm to patients who engaged in high flexion activities, including [the plaintiff]." *Id.* at *226.

The cases cited by Defendants are generally distinguishable. In *Am. Family Mut. Ins. Co. v. Electrolux Home Prods.*, expert opinions about alternative designs that had not been tested were considered reasonable alternatives, 2014 WL 2893179, at *15 (W.D. Wis. 2014). In *Oden v. Bos. Sci. Corp.*, the complaint stated that the proposed alternative design was for a retrievable filter, whereas in this case Mrs. Hyde understood her filter would remain for the rest of her life. 2018 U.S. Dist. LEXIS 102639, at *12 (E.D.N.Y. June 4, 2018). Similarly, *Simon v. Smith & Nephew, Inc.*, involved a motion on the pleadings and failed to allege that the proposed alternative design was safer. 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013). In *Pinello v. Andreas Stihl AG & Co. KG*, the court held that a proposed alternative must retain the "inherent usefulness of the defective product," but rejected the

proposed alternative because, unlike here, the plaintiff's expert testified that it was "not a substitute." 2011 WL 1302223, at *40 (N.D.N.Y. Mar. 31, 2011). In *Quintana v. B. Braun Med., Inc.*, there was no allegation of any defect; the citation to *Oden* regarding permanent versus retrievable filters is dicta in a footnote. 2018 WL 3559091, at *9 n.5 (S.D.N.Y. July 24, 2018) (citing *Oden*, 2018 U.S. Dist. LEXIS 102639, at *12). *Theriot v. Danek Med., Inc.*, involved a proposed alternative that was a completely different type of device (external neck brace compared to pedicle screw), which would be similar to arguing here that blood thinners were a reasonable alternative to filters. 168 F.3d 253, 255 (5th Cir. 1999).[1]

Here, the various alternative designs the jury can consider are reasonable alternatives. Mrs. Hyde was diagnosed with a protein C deficiency and understood that she would require blood thinners for the rest of her life and would benefit from a filter for the same period of time. Bard marketed the G2x and Eclipse filters for lifetime use, had evidence that the filter would become permanent after 6 months, and represented to the FDA that the filter was equivalent (indirectly) to the Simon Nitinol filter, a permanent device. An alternative device that is not easily retrieved does "not substantially impair the usefulness or intended purpose" of the device for Mrs. Hyde, namely to prevent clots from her lower extremities from reaching her heart and lungs. *Great N. Ins. Co.* 84 F. Supp. 3d at 657.[2]

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[1] Similarly, cases involving prescription drugs fail where the proposed alternative involves a different chemical compound. *Massa v. Genentech Inc.*, No. H-11-70, 2012 WL 956192, at *17 (S.D. Tex. Mar. 19, 2012); *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 771 (Tex. App. 2009) (proposing new drug formulation as a safer alternative).

[2] A proposed alternative design need not be tested or commercially available. "Qualified expert testimony on the issue suffices, even though the expert has produced no prototype, if it reasonably supports the conclusion that a reasonable alternative design could have been practically adopted at the time of sale." *Martin v. Michelin N. Am., Inc.*, 92 F. Supp. 2d 745, 758 (E.D. Tenn. 2000) (applying Tennessee law; citing The Restatement (Third) of Torts § 2(b), cmt. f). *See also Standard Fire Ins. Co. v. Broan Nutone*, LLC, No. 2:07cv44-KS-MTP, 2008 U.S. Dist. LEXIS 107030, at *16 (S.D. Miss. July 1, 2008) ("A competitor's contemporaneous use of the proposed design alternative for the same purpose in the same consumer market is sufficient evidence to establish a genuine issue of fact as to the existence of a feasible design alternative."). Here, Plaintiffs' expert, Dr.

III. Punitive Damages

Under Wisconsin law, punitive damages are warranted where the Defendant desires the causes or consequences, or "believes that the consequences are substantially certain to result from [its actions]." *Strenke v. Hogner*, 694 N.W.2d 296, 299 (Wis. 2005). Where a man drank 16-18 beers in 5 hours and then caused $2,000 in damages, but had never injured anyone when drinking and did not intend to injury anyone, his acts were considered "intentional" under the Wisconsin statute because they were "substantially certain to result." *Id.* at 301. Here, the evidence supports a finding that Bard's disregard for and failure to disclose the safety issues it became aware of were more likely to result in injury than an individual who drove while intoxicated (an activity that, unfortunately, people engage in every day without consequence). In contrast, Bard's conduct did not involve a single act, but sales of thousands of devices that it predicted would fracture (and determined were fracturing) at high rates, so it was virtually certain that Bard would cause harm to others due to its defective designs. Plaintiffs submit that their evidence meets this standard and should be submitted to the jury.

Robert McMeeking, has testified that Bard could have developed caudal anchors and penetration limiters sooner than it did. These safety features ultimately were incorporated into Bard's Meridian and Denali filters, and Bard knew as early as March 2006 that one of its competitors had designed anchors to reduce caudal (downward) migration by flipping two of the hooks that secured the filter to the IVC wall. The jury reasonably could conclude from this evidence that specific and reasonable alternative design changes were available when Defendants developed the G2X and Eclipse filters.

RESPECTFULLY SUBMITTED this 30th day of September, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of September 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Felice Wortman